

WHAT IS CLAIMED IS:

- 1 1. A method for inactivating a pathogen in a protein solution which
2 comprises adding to said protein solution either separately or together:
3 (a) a detergent; and
4 (b) an ester of a carboxylic acid formed between a carboxylic acid selected
5 from the group consisting of monocarboxylic acids, dicarboxylic acids
6 and tricarboxylic acids, and an alcohol which is a member selected
7 from monohydroxy alcohols, polyhydroxy alcohols, and combinations
8 thereof, to make a preparation, said ester being present in said
9 preparation in a concentration of from about 0.001% to about 2%
10 (w/w) and said detergent being present in a concentration of from
11 about 0.001% to about 2 % (w/w);
12 and incubating said preparation for an amount of time sufficient to inactivate
13 said pathogen.
14
1 2. The method according to claim 1 wherein said carboxylic acid is a
2 member selected from the group consisting of hydroxy-monocarboxylic acids, hydroxy-
3 oligo-carboxylic acids, keto-monocarboxylic acids, keto-oligocarboxylic acids and
4 combinations thereof.
5
1 3. The method according to claim 1 wherein said alcohol is a member
2 selected from the group consisting of ethanol, n-butanol, dodecanol, tetradecanol,
3 hexadecanol, octadecanol, eicosanol, glycerol, threitol, erythritol, pentitols and hexitols,
4 pentose or hexose monosaccharide, and pentose or hexose oligosaccharide.
5
1 4. The method according to claim 1 wherein said alcohol is a short chain
2 alcohol.
3
1 5. The method according to claim 1 wherein said carboxylic acid is a
2 member selected from the group consisting of acetic acid, butyric acid, adipic acid, sebacic
3 acid, succinic acid, and fumaric acid.
4
1 6. The method according to claim 1 wherein said ester is a member
2 selected from the group consisting of mono-, di- and triglycerides of short chain fatty acids.

1 7. The method according to claim 6 wherein said ester is a member
2 selected from the group consisting of monoacetyl glycerides, diacetylglycerides,
3 triacetylglycerides, monobutyryl glycerides, dibutyrylglycerides, and tributyrilglycerides.

1 8. The method according to claim 2 wherein said carboxylic acid is a
2 member selected from the group consisting of lactic acid, glycolic acid, malic acid, tartaric
3 acid, monoacetyl tartaric acid, diacetyl tartaric acid, citric acid, isocitric acid, and gluconic
4 acid.

1 9. The method according to claim 1 wherein said ester is selected from
2 the group of citric acid esters consisting of triethyl citrate, tributyl citrate, and acetyl
3 triethyl citrate.

1 10. The method according to claim 2 wherein said carboxylic acid is a
2 member selected from the group consisting of pyruvic acid and oxaloacetic acid.

1 11. The method according to claim 1 wherein said detergent is a member
2 selected from the group consisting of an alkali metal salt of a fatty acid, a cholic (bile) acid, a
3 sodium- or calcium stearyl lactyl 2-lactate, a short-chain ($< C_{14}$) fatty acid monoglyceride, a
4 short-chain ($< C_{14}$) fatty acid diglyceride, sugar fatty acid esters, sugar glycerides, sorbitan-
5 fatty acid esters, sorbitan-polyoxyethylene-fatty acid esters (polysorbates), and octoxynol 9
6 (triton X-100), nonoxynol 9 and combinations thereof.

1 12. The method according to claim 1, wherein said detergent is a member
2 selected from the group consisting of a fatty acid monoglyceride which is esterified with a
3 member selected from acetic acid, lactic acid, citric acid, tartaric acid, monoacetyl tartaric
4 acid, diacetyl tartaric acid and combinations thereof; and a fatty acid diglyceride which is
5 esterified with a member selected from acetic acid lactic acid, citric acid, tartaric acid,
6 monoacetyl tartaric acid, diacetyl tartaric acid and combinations thereof.

1 13. The method according to claim 11 wherein said detergent is Tween 80.

1 14. The method according to claim 1 wherein the concentration of said
2 ester in said preparation is from about 0.01% to about 1 % (w/w).

1 15. The method according to claim 14 wherein the concentration of said
2 ester in said preparation is from about 0.1% to about 0.5 % (w/w).

1 16. The method according to claim 1 wherein the concentration of said
2 detergent is from about 0.5% to about 1 % (w/w).

1 17. The method according to claim 1 wherein said preparation is incubated
2 for at least about 0.5 min.

1 18. The method according to claim 1 wherein said preparation is incubated
2 at a temperature from about 0 °C to about 60 °C

1 19. The method according to claim 1 wherein said protein is enriched from
2 a natural source by chromatographic or precipitation methods.

1 20. The method according to claim 1 wherein said protein is a member
2 selected from the group consisting of a recombinantly produced protein and a transgenically
3 produced protein.

1 21. The method according to claim 1 wherein said protein is a member
2 selected from the group consisting of plasma, coagulation factors, immunoglobulin, albumin,
3 antithrombin III, Cl-esterase inhibitor, α_1 -antitrypsin (α_1 -proteinase inhibitor) and FEIBA.

1 22. The method according to claim 1, wherein said coagulation factor is a
2 member selected from factor IX, and factor X.

1 23. The method according to claim 1 wherein said pathogen is a lipid-
2 enveloped virus.

1 24. The method according to claim 23 wherein said pathogen is a member
2 selected from the group consisting of Hepatitis virus, human immunodeficiency virus, bovine
3 viral diarrhoea virus, herpes virus, and pseudorabies virus and combinations thereof.

1 25. A method for enhancing the pathogen inactivating properties of a
2 composition comprising at least one detergent said method comprising adding to said
3 composition a carboxylic acid ester formed between a carboxylic acid selected from the
4 group consisting of monocarboxylic acids, dicarboxylic acids and tricarboxylic acids, and an

5 alcohol which is a member selected from monohydroxy alcohols, polyhydroxy alcohols, and
6 combinations thereof.

1 **26.** The method according to claim **25** wherein said ester is added to said
2 composition in a concentration of from about 0.001% to about 20 % (w/w).

1 **27.** The method according to claim **26** wherein said ester is added to said
2 composition in a concentration of from about 0.1% to about 10 % (w/w).

1 **28.** The method according to claim **27** wherein said ester is added to said
2 composition in a concentration of from about 2% to about 5 % (w/w).

1 **29.** The method according to claim **25** wherein said detergent is present in
2 said composition in a concentration of from about 0.01% to about 20 % (w/w).

1 **30.** The method according to claim **29** wherein said detergent is present in
2 said composition in a concentration of from about 5% to about 10 % (w/w).

1 **31.** The method according to claim **25** wherein said carboxylic acid is a
2 member selected from the group consisting of hydroxy-monocarboxylic acids, hydroxy-
3 oligo-carboxylic acids, keto-monocarboxylic acids, keto-oligocarboxylic acids and
4 combinations thereof.

1 **32.** The method according to claim **25** wherein said alcohol is a member
2 selected from the group consisting of ethanol, n-butanol, dodecanol, tetradecanol,
3 hexadecanol, octadecanol, eicosanol, glycerol, threitol, erythritol, pentitols and hexitols,
4 pentose or hexose monosaccharide, and pentose or hexose oligosaccharide.

1 **33.** The method according to claim **25** wherein said alcohol is a short chain
2 alcohol.

1 **34.** The method according to claim **25** wherein said carboxylic acid is a
2 member selected from the group consisting of acetic acid, butyric acid, adipic acid, sebacic
3 acid, succinic acid, and fumaric acid.

1 **35.** The method according to claim **25** wherein said ester is a member
2 selected from the group consisting of mono-, di- and tri-glycerides of short chain fatty acids.

1 **36.** The method according to claim **35** wherein said ester is a member
2 selected from the group consisting of monoacetyl glycerides, diacetylglycerides,
3 triacetylglycerides, monobuteryl glycerides, dibutrylglycerides, and tributrylglycerides.

1 **37.** The method according to claim **31** wherein said carboxylic acid is
2 selected from the group consisting of lactic acid, glycolic acid, malic acid, tartaric acid,
3 mono- and diacetyl tartaric acid, citric acid, isocitric acid, and gluconic acid.

1 **38.** The method according to claim **31** wherein said ester is selected from
2 the group of citric acid esters consisting of triethyl citrate, tributyl citrate, and acetyl triethyl
3 citrate.

1 **39.** The method according to claim **31** wherein said carboxylic acid is
2 selected from the group consisting of pyruvic acid and oxaloacetic acid.

1 **40.** The method according to claim **25** wherein said detergent is a member
2 selected from the group consisting of an alkali metal salt of a fatty acid, a cholic (bile) acid, a
3 sodium- or calcium stearyl lactyl 2-lactate, a short-chain (< C14) fatty acid monoglyceride,
4 a short-chain (< C14) fatty acid diglyceride, sugar fatty acid esters, sugar glycerides, sorbitan-
5 fatty acid esters, sorbitan-polyoxyethylene-fatty acid esters (polysorbates), and octoxynol 9
6 (triton X-100), nonoxynol 9 and combinations thereof.

1 **41.** The method according to claim **25**, wherein said detergent is a member
2 selected from the group consisting of a fatty acid monoglyceride which is esterified with a
3 member selected from acetic acid, lactic acid, citric acid, tartaric acid, monoacetyl tartaric
4 acid, diacetyl tartaric acid and combinations thereof; and a fatty acid diglyceride which is
5 esterified with a member selected from acetic acid lactic acid, citric acid, tartaric acid,
6 monoacetyl tartaric acid, diacetyl tartaric acid and combinations thereof.

1 **42.** The method according to claim **40** wherein said detergent is Tween 80.